Application No.: 10/581,094

Attorney Docket No.: RANB3003/REF/LES

LISTING AND AMENDMENT OF THE CLAIMS

- 1. (Currently Amended) A method to determine an analyte concentration of an anticoagulated plasma by calculation based on results of measurements performed on a mixture of a blood sample and a liquid reagent, comprising the steps of
 - a) mixing a volume of said blood sample with a five-fold, or more, volume of said liquid reagent,
 - b) performing at least two measurements on the obtained mixture, the result of at least one of which correlates with the hematocrit of said blood sample and the result of at least one of which correlates with said analyte concentration, and
 - c) computing the results from the measurements, while either providing for the precise correspondence of the volumes of the components which are mixed in step a) with the volumes according to the test protocol or the known-value of the hematocrit of said blood sample and thereby determining said analyte concentration of said anticoagulated plasma by calculation as (i) a function of the results of the at least two measurements of step (b) or (ii) a function of the results of the at least two measurements of step (b) and the known value of the hematocrit of said blood sample.
- 2. (Previously Presented) The method according to claim 1, wherein,
 - a) the volume of blood in said mixture is within the range of 50% to 150% of the volume of blood according to the test protocol,
 - b) the volume of reagent in said mixture is within the range of 70% to 120% of the volume of reagent according to the test protocol, and
 - c) computing the results to determine the analyte concentration when the hematocrit of the blood sample is known.
- 3. (Previously Presented) The method according to claim 1, wherein said volume of blood in a) according to the test protocol is in the range of 5 to 40 μ L and said volume of reagent according to the test protocol is in the range of 100 to 1000 μ L.

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4. (Previously Presented) The method according to claim 1, wherein said volume of blood in a) is in the range of 5 to 20 μ L and said volume of reagent is in the range of 150 to 600 μ L.

- 5-6. (Canceled).
- 7. (Previously Presented) The method according to claim 1, wherein said determination of analyte concentration is calibrated with anticoagulated plasma that has been subjected to an anticoagulation process by addition of an anticoagulant selected from the group consisting of sodium, potassium and lithium salts of citrate, isocitrate, EDTA, oxalate, heparin and hirudin.
- 8. (Original) The method according to claim 1, wherein said anticoagulated plasma is a fluid derived from blood, which is selected from the group consisting of blood derived fluids composed of serum, heparinized plasma, hirudinized plasma, oxalated plasma, citrated plasma, isocitrated plasma, EDTA-plasma and heat-treated plasma.
- 9. (Previously Presented) The method according to claim 1, wherein said determination of analyte concentration is calibrated with anticoagulated blood, with known analyte concentration in the corresponding anticoagulated plasma, that has been subjected to an anticoagulation process by addition of an anticoagulant selected from the group consisting of sodium, potassium and lithium salts of citrate, isocitrate, EDTA, oxalate, heparin and hirudin.
- 10. (Previously Presented) The method according to claim 1, wherein said analyte is selected from the group consisting of prothrombin time (PT), fibrinogen, fibrinogen degradation products, fibrin degradation products (D-dimer), activated partial thromboplastin time (APTT), activated clotting time (ACT), C-reactive protein (CRP), cholesterol, and glucose.
- 11. (Previously Presented) The method according to claim 1, wherein said measurement the result of which correlates with said hematocrit in b) is based on one or more measurements of light with wavelengths in the range of 800 nm to 1100 nm.

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12. (Original) The method according to claim 1, wherein said two or more measurements in b) are performed at ambient temperature in the range of 18° C to 40°C.

- 13. (Original) The method according to claim 1, wherein said reagent in a) contains 0.1 g/L, or more, fibringen.
- 14. (Currently Amended) The method according to claim 1, wherein said analyte concentration is PT expressed in <u>INRInternational Normalized Ratio (INR)</u>, wherein, prior to said determination of analyte concentration in anticoagulated plasma, the analyte concentration is re-expressed in PT%.
- 15. (Original) The method according to claim 1, wherein clotting time of said mixture in a) is one of the at least one measurement that correlates with said analyte concentration in b).
- 16. (Withdrawn) A device for determining an analyte concentration of an anticoagulated plasma according to claim 1 comprising
 - a) a holder for receiving a container containing liquid reagent from a specific lot, which container receives on operation of the device a blood sample corresponding to said anticoagulated plasma for admixture with the liquid reagent,
 - b) an energy source,
 - c) a data processor for computing the results from the measurements while either providing for the precise correspondence of the volumes of the components which are mixed in step a) of claim 1 with the volumes according to the test protocol or the known value of the hematocrit of the blood sample,
 - d) a read-only memory comprising stored calibration data necessary to determine the analyte concentration of the anticoagulated plasma adapted to said specific lot of reagent

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e) a means for performing two or more measurements on the same mixture of blood and liquid reagent, the result of at least one of which correlates with the hematocrit of said blood sample and the result of at least one of which correlates with the analyte concentration,

- f) a display that shows the results, and
- g) a control means for user control of the device.
- 17. (Withdrawn) An equipment kit equipped with an identification mark comprising a device according to claim 16, having an identification mark that is related to the identification mark of the equipment kit andone or several liquid reagent(s) in container(s) equipped each with an identification mark related to the identification mark of the equipment kit, wherein the device comprises a read-only memory containing calibration data for the determination of an analyte concentration in an anticoagulated plasma using the reagents which are a part of the same equipment kit as the device.